

The Applicants hereby submit an Information Disclosure Statement, Form PTO-1449, to comply with 37 CFR § 1.98(a)(1) listing the references already of record with the instant Specification and/or the International Search Report. As will be noted, this Information Disclosure Statement calls a number of references, which might be considered relevant, to the attention of the Office. The fact that these are in fact "prior art" and/or relevant to the prosecution is, however, not admitted. It is understood that, during examination, the Office will make an independent search and will identify any relevant prior art under 37 CFR § 1.104(a).

REMARKS

The Applicants acknowledge the Office's Final Rejection with appreciation. Claims 22-24 and 26-40 are pending in the application.

The Office has withdrawn rejections of claims 22-24 and 26-39 under 35 U.S.C. §§ 101, 112 and 102 in view of applicants' amendments.

To begin, the Office submits that the Applicant's amendment necessitated the new ground of rejection, presented in the instant Office Action and, therefore, the action was made final. The Applicants question the prematurity of the final rejection, according to MPEP § 706.07 (c) and hereby petition for withdrawal of the finality of the instant Office Action.

With the Response and Amendment, filed December 16, 2004, claim 22 was amended to encompass only the *Klebsiella pneumoniae* membrane protein of SEQ ID No. 2. No additional limitations were introduced into the claims with the amendment. In the Response, the Applicants discussed the improved immunity which is demonstrated upon intranasal administration of compositions comprising the *Klebsiella pneumoniae* membrane protein. The Applicants discussed that it is this surprising activity which distinguishes the instant invention from the cited prior art. The limitation to intranasal administration was an element of the claim as originally filed and, therefore, may not constitute a basis for the new grounds of rejection under 35 U.S.C. § 103(a) in the instant Office Action. The Applicants

submit that the Office improperly made the instant Action final in view of the newly cited basis for rejection.

The Applicants hereby petition for withdrawal of the instant Office Action.

Moving on, Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to claim with particularity. The Applicants acknowledge the Office notation of the improper use of "The" with reference to The Method of Claim 22, which is the first mention of a method and, therefore, should be identified with the article "A". With this Response After Final, the Applicants amend Claim 22, thereby providing the requested definition.

The Office rejects Claims 22-24 and 26-39 under 35 U.S.C. § 103(a) as being obvious over Rauly, et al., (Research in Immunology 1998, Vol. 149:99) in view of newly cited Cooper, et al., (Journal of Infectious Diseases, 1983, 147:312-317).

The Office contends that Rauly, et al. teach a method of using *Klebsiella pneumoniae* for improving immunity, but Rauly, et al. do not teach intranasal administration. Cooper, et al. teach intranasal administration of inactivated *Klebsiella pneumoniae* bacteria. The Office submits that it would be *prima facie* obvious to a person of ordinary skill in the art to combine the teaching of Rauly, et al. with the teaching of Cooper, et al. to arrive at the claimed invention.

To make the instant combination rejection, the Office must demonstrate a basis in the art for combining the references. The mere fact that references can be combined does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000); *In re Mills*, 916 F2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). MPEP § 2143.01. The Office has not demonstrated this to be true.

The Office states that it would be *prima facie* obvious for one skilled in the art to combine the method of Rauly, et al. with the teaching Cooper, et al. for improved immunity. The Applicants submit that the Office has not identified a suggestion or

motivation to combine the prior art references. As stated in the instant Office Action, "Raully, et al. teach that the conjugate generated strong antibody response even in the absence of any adjuvant." Since a strong antibody response was demonstrated by Raully, et al., the Applicants submit that there is no motivation in the cited Raully, et al. to combine the method with the teaching of Cooper, et al.

The Office states, "One of ordinary skill in the art would have been motivated to administer the pharmaceutical composition of Raully, et al. intranasally by the teachings of Cooper, et al. that protection from disease also follows after intranasal immunization of *Klebsiella pneumoniae* and antibodies develop in the serum after intranasal immunization (i.e. improving immunity)." In establishing a *prima facie* case of obviousness, the level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). Therefore, the Office basis for the motivation to combine the references, according to one of ordinary skill in the art, is improper.

Absent such an express showing in the prior art to combine the references to teach the instant invention, the Applicants submit that the Office has used impermissible hindsight reasoning by using the Applicant's teaching as a blueprint to hunt through the prior art for the claimed elements and combine them as claimed.

In establishing a *prima facie* case of obviousness, a reasonable expectation of success is necessary. The Office asserts that it would be obvious to a person of ordinary skill in the art to try intranasal administration of the pharmaceutical composition of Raully, et al. to arrive at the instant invention. The Applicants assume that the Office has read the entire Cooper, et al. abstract, as an incomplete copy was provided to the Applicants with the instant Office Action. The Applicants have obtained a complete abstract of the cited Cooper, et al. In the complete Cooper, et al. abstract, it is disclosed that, "Low levels of antibodies develop in serum after intranasal immunization." Intranasal administration of inactivated *Klebsiella pneumoniae* bacteria generated low serum levels of antibody. Therefore, Cooper, et al. actually teach away from the claimed method of improving immunity, demonstrated by an enhanced systemic antibody response, following intranasal

administration. In contrast to the teaching of the prior art, the instant invention provides an unexpectedly enhanced capacity to achieve a serum antibody response through intranasal immunization.

In view of these arguments the Applicants submit that the Office has not established a *prima facie* case of obviousness. In light of these remarks, reconsideration and withdrawal of the prior art rejection is respectfully solicited.

The Office rejects Claims 22-24 and 26-39 under 35 U.S.C. § 103(a) as being obvious over Haeuw, et al., (European Journal of Biochemistry, 1998, 255:446-454) in view of Cooper, et al., (Journal of Infectious Diseases, 1983, 147:312-317). The Office contends that Haeuw, et al. teach a method of using *Klebsiella pneumoniae* for improving immunity, but Haeuw, et al. do not teach intranasal administration. Cooper, et al. disclose intranasal administration of inactivated *Klebsiella pneumoniae* bacteria. The Office concludes that it would be *prima facie* obvious to a person of ordinary skill in the art to combine the teaching of Haeuw, et al. with the teaching of Cooper, et al. to arrive at the claimed invention. This combination fails for the same reasons noted above, namely, there is no requisite suggestion or motivation in Haeuw, et al. to combine the references. Moreover, the cited Cooper, et al. reference actually teaches away from an enhanced serum antibody response associated with intranasal administration. Furthermore, the Applicants note that the cited Haeuw, et al. has a publication date of July 1998 (see enclosed abstract) which is after the French priority date of March 27, 1998 and therefore, may not be applied as a prior art reference.

In view of these arguments the Applicants submit that the Office has not established a *prima facie* case of obviousness. Reconsideration and withdrawal of the prior art rejection is respectfully solicited.


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Accordingly, withdrawal of the finality of the instant Office Action, entry of the present amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,
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Enclosure: Listing of Claims; Information Disclosure Statement, Form PTO-1449;
Haeuw, et al. abstract; Extension Fee, one (1) month and Postal Card
Receipt

THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.